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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,823	07/24/2006	Peter Kinast	19497-002US1	8435
26191 7590 08/05/2009 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER CARPENTER, WILLIAM R				
ART UNIT 3767		PAPER NUMBER		
NOTIFICATION DATE 08/05/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/542,823

Applicant(s)

KINAST ET AL.

Examiner

WILLIAM CARPENTER

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-60 and 62-106 is/are pending in the application.
- 4a) Of the above claim(s) 88-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-60 and 62-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 56-58, 60, 62-64, 76, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") in view of USPN 2,697,438 ("Hickey").

Regarding Claims 56, 58, 60, 76, 78, and 79, Henderson discloses a needle (10) for penetrating a membrane having a pointed end (Figure 2) provided with a penetrating tip (Figure 3) and with an opening (13) for letting a liquid in and out in a main direction which is substantially parallel to the longitudinal extension of the needle (Figure 2). Henderson discloses that the penetrating tip is designed with a point (12) to initially prick a membrane when the membrane is penetrated and that the outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded (Figure 6) so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material (Col. 1, Ln. 50-63; Col. 2, Ln. 22-46).

Henderson discloses the penetrating tip to be designed with a circular cross section having a symmetry (Fig. 6 and Fig. 2) at a longitudinal center line of the needle (when viewed from above as in Fig. 2). However, Henderson fails to disclose that the point is on the longitudinal center line when observed from all viewing angles. However, Hickey discloses a needle (1) designed to prevent coring, a task mutually shared by the needle of Henderson. Hickey discloses that shape of the penetrating tip (Fig. 2) of the needle should be altered such that the point (5) of the needle lies directly on the longitudinal center line (A) of the needle (Fig. 2). It would have been obvious for one having ordinary skill in the art at the time the invention was made to alter the shape of

the penetrating point of the needle of Henderson such that the point lies on the longitudinal axis when observed from all viewing angles, as disclosed by Hickey, thereby only achieving the expected results of providing a needle penetrating tip shape that is art recognized for preventing needle coring. While neither Henderson nor Hickey disclose the distribution of forces about the penetrating tip radiating from the longitudinal center line, it is held that the position of the modified point of Henderson in conjunction with the disclosed circular symmetry of the penetrating tip, that an infinite number of substantially equally sized forces in different directions radial to the longitudinal center line would be produced, the forces counteracting one another such that the needle will tend not to deviate from the initial penetration direction when the needle penetrates a membrane. It is important to note that it is not possible for the Office to perform experimental testing of both Applicant's claimed invention and those in the prior art in order to definitively ascertain the exact distribution of forces. As such, Examiner must rely upon the claimed structure in order to differentiate whether or not the prior art is capable of satisfying the claimed functional language. As the device of Henderson, as modified by Hickey, discloses the same structure as claimed by Applicant, absent any explicit showing of evidence to the contrary, it is held that the prior art of Henderson and modified by Hickey is capable of satisfying the claimed functional language.

Regarding Claim 57, Henderson discloses that the inner edge of the opening is rounded (Fig. 6).

Regarding Claims 62, 80, and 81, both Henderson and Hickey discloses the pointed end to have a shape substantially corresponding to part of an imaginary cone, the tip of which coincides with the point (Fig. 3; Henderson) (Fig. 2; Hickey).

Regarding Claims 63 and 82, both Henderson and Hickey discloses that the opening is formed such that a opening thereof is arranged on one and the same half of the cross-section of the needle (Fig. 2 and 3; Henderson) (Fig. 2 and 3; Hickey). It is important to note that the cross-section of the needle may be assumed at any position.

Regarding Claims 64 and 83, Henderson illustrates the pointed end to be provided with a basic shape in accordance with a lancet bevel cut (Fig. 2).

5. Claims 59 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") and US Patent No. 2,697,438 ("Hickey") as applied to Claim 58 or 76 above, and further in view of and US Patent No. 4,889,529 ("Haendl").

Regarding Claims 59 and 77, Henderson in view of Hickey discloses the invention substantially as claimed except that the cross section is substantially triangular with rounded edges. However, Haendl discloses a needle (30) specifically designed as to be non-coring (Abstract). Haendl discloses that the needle should have a penetrating tip (Fig. 5) having a cross section that is substantially triangular with rounded edges (33). It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the cross section of the penetrating tip of the modified device of Henderson having a substantially triangular cross section with rounded edges, as disclosed by Haendl, thereby only achieving the expected results of

providing a needle having a penetrating tip shape that is explicitly disclosed as preventing coring.

6. Claims 65 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") and US Patent No. 2,697,438 ("Hickey") as applied to Claims 56 or 58 above, and further in view of and US Patent No. 5,515,871 ("Bittner").

Regarding Claims 65 and 84, Henderson discloses the invention substantially as claimed except that pointed end is provided with a basic shape in accordance with a back bevel cut. However, Bittner discloses various needles (10, 2, and 30) having either a lancet bevel (Fig. 3) or a back bevel (Fig. 2), illustrating the two bevels to be obvious variants of one another. As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to modify the tip of the needle of Henderson to comprise a back bevel, as disclosed by Bittner, thereby only achieving the expected results of replacing one needle point end bevel with an art recognized alternative bevel.

7. Claims 66-69, 72, 73, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson"), US Patent No. 5,515,871 ("Bittner"), and US Patent No. 2,697,438 ("Hickey") as applied to Claims 58, 65, or 84 above, and further in view of US Patent No. 4,889,529 ("Haindl").

Regarding Claims 66, 68, 72, 73, and 86, Henderson in view of Bittner discloses the invention substantially as claimed except for explicitly disclosing the angle of the back bevel cut. However, Bittner does illustrate the back bevel cut to be to the order of

45 degrees (Fig. 2B). Haindl illustrates a similar needle (60) which explicitly has a point bevel of 30 degrees (Fig. 8). As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the modified needle of Henderson to include a beveled point of 30 degrees, as disclosed by Haindl, thereby only achieving the expected results of providing a well-known tip bevel angle to obtain a predictable outcome. It has been held that a value within a range anticipates said range.

Regarding Claims 67 and 69, Henderson in view of Bittner and Haindl discloses the invention substantially as claimed except that bevel cut has a tip angle in the interval of 50 to 100 degrees. However, one having ordinary skill in the art would reasonably recognize and appreciate that the tip angle is a result effective variable as established by Bittner and more specifically Haindl. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the bevel cut of the modified device of Henderson to be within an interval of 50 to 100 degrees and more specifically to approximately 75 degrees, since it has been held that discovering the optimum value of a result effective variable requires only routine and customary skill in the art.

8. Claims 70, 71, 74, 75, 85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson"), US Patent No. 5,515,871 ("Bittner"), and US Patent No. 2,697,438 ("Hickey") as applied to Claims 56, 65, 69 or 84 above, and further in view of US Patent No. 6,517,523 ("Kaneko").

Regarding Claims 70, 71, 74, 75, 85 and 87, Henderson in view of Bittner and Haindl discloses the invention substantially as claimed except for disclosing the second

grind angle of the back bevel cut. However, Kaneko discloses a needle (1) having a second grind angle of between at least 115 to 135 degrees (Figure 1C), thereby establishing the second grind angle as a result effective variable. However, Kaneko fails to explicitly disclose that the second grind angle is limited to the interval of 50 to 140 degrees, and more specifically to about 100 degrees. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the second grind angle of the modified device of Henderson to comprise a second grind angle of approximately 100 degrees, within the range suggested by Bittner, since it has been held that determining the optimum value for a result effective variable requires only routine skill in the art thereby only achieving the expected results of providing a suitable second grind angle for a needle to obtain a predictable outcome.

Response to Arguments

9. Applicant's arguments filed 12 May 2009 have been fully considered but they are not persuasive.

Applicant argues that the "interpretation of 'arranged to lie substantially on a longitudinal centre line of the needle,'... cannot reasonably be interpreted to mean simply appearing to be coincident with a particular midpoint of single axis of symmetry when observed from a particular angle". However, this is not found to be persuasive. In the instant case the phrase "on" is afforded its broadest reasonable interpretation as "a function word to indicate the location of something or position in close proximity therewith". The claims do not require that the point lies on the longitudinal center line in

all plane of reference, and in fact the point of the needle of Henderson may be conceived to lie on the longitudinal center line when observed as seen in Fig. 1 or Fig.

2. Furthermore, as was previously recited in the above rejection and the rejection mailed 04 February 2009 any traversal to this position is obviated by the inclusion of the Hickey reference which illustrates a needle having a point lying on the longitudinal center line when observed from all planes of reference.

Applicant argues that "[t]he rounded edged needle disclosed by Henderson appears to address the problem of coring for a single-use penetration, even in the context of a synthetic membrane. Thus, one of ordinary skill in the art would have no reason to further modify the single-use needle disclosed by Henderson". However, this is not found to be persuasive. One having ordinary skill in the art would reasonably recognize and appreciate that even were the invention of Henderson adequate at preventing coring this does not mean that the needle could not be further improved, particularly with respect to the teachings of a secondary reference. Examiner submits that it would be obvious for one having ordinary skill in the art to try various features disclosed with respect to the prior art of non-coring needles in an attempt to provide potential improvements to the needle of Henderson.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that "Hickey therefore discloses a completely different solution to the problem of coring. Even though Hickey discloses a point on the center line, Hickey does not indicate that there is any advantage when using a needle to repeatedly pierce a membrane with locating the point of a needle along a longitudinal centre line of a needle". However, this is not found to be persuasive. The fact that Hickey utilizes a solution different from the invention of Henderson to solve the problem of needle coring does not obviate a combination between the teachings of Hickey and Henderson, and in fact forms the crux of the proposed obvious combination. One having ordinary skill in the art would reasonably be expected to look towards the teachings of others to find ways in which the needle of Henderson might be further improved. Hickey discloses another technique which may be used to help prevent coring, and one having ordinary skill in the art would reasonably expect and appreciate success were the features of both inventions combined to form a single non-coring needle.

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combination of the feature(s) of the Henderson and Hickey reference relies on the customary motivation of one having ordinary skill in the art to seek ways in which an invention

could be further improved by looking at other solutions found within the art. One having ordinary skill in the art would reasonably recognize and appreciate that attempting to solve a problem (in the instant case needle coring) utilizing multiple solutions would provide reasonable expectation of success. By combining the feature(s) of the Henderson and Hickey reference only the expected results of creating a needle that benefits from both manners of preventing coring.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. This is a continued examination of Applicant's earlier Application No. 10/542,823. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
07/21/2009
/Kevin C. Simons/
Supervisory Patent Examiner, Art Unit 3767

